JUL 18 2002

Attachment 2

Micomed – Posterior Doublerod System
510(K) Summary

Prepared July 1, 2002

Tradename:	Micomed Posterior Doublerod System
Generic Name	Spinal Fixation Device System
Classification:	Class II MNI and MNH, 21CFR888.3070 KWP, 21CFR888.3050
Company:	Micomed Ortho GmbH & Co. KG Schorndorfer Strasse 96 Schorndorf 73614 Germany Phone: 011 49 71 81 48 99 85 87 Fax: 011 49 71 81 48 99 84 info@micomed.com
Contact:	Corrine M. Taflinger, RAC RA Consultant (858) 481-1638
Predicate Devices	Cross Medical Synergy™ Spinal System, 510(k) # K974749 Depuy Inc. Moss® Spinal System, 510(k) #984378
Description:	The Micomed Posterior Doublerod System is a low profile, top loading spinal fixation system available in titanium and stainless steel. The system consists of pedicle screws, polyaxial screws*, open and closed hooks, and fluted and threaded rods. A set of instruments is available for use with the Micomed Posterior Doublerod System. * polyaxial screws are only available in titanium
Material:	The components of the Micomed Posterior Doublerod System are available in titanium in conformance with ASTM F136 as well as Stainless Steel in conformance with ASTM F1314. Polyaxial Screws are only available in titanium.

Indications:	***510(K) Summary - continued*** The Micomed Posterior Doublerod System is a pedicle screw system indicated for the treatment of severe spondyloisthesis (Grades 3 and 4) at the L5-S1 vertebra in skeletally mature patients receiving fusion by autologous bone graft having implants after the attainment of a solid fusion. The Micomed Posterior Doublerod System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of deformities of the thoracic, lumbar, and sacral spine: degenerative spondyloisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). When used as a non-pedicle screw fixation system, the Micomed Posterior Doublerod System is also intended for scoliotic, lordotic, or kyphotic deformities such as scoliosis, Scheuermann's disease, degernerative disk disease defined as back pain of discogenic origin with degeneration of the disk confirmed by patient history and radiographic studies, and fractures of the posterior thoracolumbar spine from levels T4 to S1.
Testing and Performance:	The polyaxial screw, to be used with the Micomed Posterior Doublerod System, has been shown to have acceptable biomechanical performance per ASTM F 1717-96 and to function in an equivalent manner to the polyaxial screws currently used in the predicate device systems.
Substantial Equivalence:	The Micomed polyaxial screw for use with the Posterior Doublerod System is substantially equivalent with respect to intended use, design, and performance to the Cross Medical polyaxial screw (as part of the Synergy Spinal System) cleared for market entry under 510(k) # K974749 on March 13, 1998, and the Depuy Moss® Spinal System cleared for market entry under 510(k) #984378 on December 30, 1998.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2002

Micomed Ortho GmbH & Co. KG
c/o Corrine M. Taflinger, RAC
Regulatory Affairs Consultant
13195 Seagrove Street
Lake Forest, California 92130

Re: K021275
Trade/Device Name: Micomed Posterior Doublerod System
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: April 17, 2002
Received: April 22, 2002

Dear Ms. Taflinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

Statement of Indication for Use

510(k) Number: K021275

Device Name: Micomed Posterior Doublerod System

Indications for Use:

The Micomed Posterior Doublerod System is a pedicle screw system indicated for the treatment of severe spondyloisthesis (Grades 3 and 4) at the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Micomed Posterior Doublerod System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of deformities of the thoracic, lumbar, and sacral spine: degenerative spondyloisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

When used as a non-pedicle screw fixation system, the Micomed Posterior Doublerod System is also intended for scoliotic, lordotic, or kyphotic deformities such as scoliosis, Scheuermann's disease, degernerative disk disease defined as back pain of discogenic origin with degeneration of the disk confirmed by patient history and radiographic studies, and fractures of the posterior thoracolumbar spine from levels T4 to S1.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use_____
(Per 21 CFR 801.109)

for Mark N Milhous (Optional Format 1-2-96)
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021275